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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,832	03/22/2001	Richard L. Mueller	5756-0012.30	6135
20583	7590	09/22/2005	EXAMINER	
JONES DAY			SHAY, DAVID M	
222 EAST 41ST ST			ART UNIT	
NEW YORK, NY 10017			PAPER NUMBER	

3739

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/816,832

Applicant(s)

MUELLER

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 27, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 and 15 is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant argues that Spears is not disclose "a fiber optic bundle... adapted for introduction into and slightly associated with the catheter lumen after the catheters distal and sleeve is position within the target region in the guide wire is removed." It is further argued that the examiner's submission that the disclosure of Spears et al. and column 8, lines 11 to 18 and 31 to 45 containing the language "the usual guide wire is replaced with optic fiber 30." has been misconstrued by the examiner. And that this passage refers to the use of an optical fiber. Instead of the guide wire and not the use of a guide wire and optical fiber in succession. In support of this assertion applicant points to column 8, lines 3 to 15 of Spears et al. wherein Spears discusses the use of a guide wire as part of the prior art. The examiner must respectfully disagree, a careful reading of Spears, for example column 9, lines 19 to 27 and lines 36 to 41 and lines 62 to 65. All discuss the use of a guide wire sometimes in conjunction with optical fiber. Thus clearly, the use of an guide wire is not merely part of the prior art, which is substituted for by an optical fiber in the method of Spears et al. is further noted that in the previously referred to passage at column 8, lines 31 to 45. Spears discusses the insertion of the optical fiber after the balloon has already been inflated clearly. The catheter was guided to the point in the blood vessel and could be inflated by the use of a guide wire as was already known the prior art.

With regard to claims 1 and 3 to 5 applicant makes the same arguments has put forth with regard to claims six to nine and further argues that the newly claimed step of "intermittently injecting the light transmissible fluid and a contrast fluid through the catheter into the catheters distal and sleeve" is not taught by the applied references. The former argument is not

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convincing. In view of the examiner for remarks above. The latter argument is not convincing. In view of their the amended rejection, including Unger et al. similarly the rejection of claim to argued us patentable on the same basis as claims 1 and 3 to 5 is also proper.

With regard to the rejection of claims 10 to 12. Applicant argues that neither of Bella, nor Altman discloses "a flexible, not inflatable, translucent distal and sleeve joined to the main body sleeve" or "a fiber optic bundle have a light diffusing tip." wherein "light scattering" is produced in part by the translucent sleeve in the tip. The examiner must respectfully disagree. A careful reading of the disclosure at column 8, lines 45 to 57. Clearly shows that the spherical lenses disburse a portion of the laser beams. Therefore the spherical lens in figure 8, will similarly dispersed the laser beams. Further regarding the disclosure related to Figures 8 and 9, e.g. column 9 line 19 through column 10, line 55, especially lines 50 through 56 wherein dispersion of the beam through the micro lens on the end of the fiber is discussed. The dispersion caused by the plurality of micro spheres is discussed in lines 57 through 59 the tube, which forms window 110 is taught of being made of quartz or sapphire (see column 9, lines 64 through 65) as high refractive index material in the path of the light will cause further dispersion thereof. With regard to applicant's discussion of the mirrored portion, applicant appears to be laboring under the misapprehension that the claim language requires that light be transmitted throughout the entire circumference of the sleeve. However, the claim merely requires that the light be transmitted along the length of the sleeve. Even assuming this limitation were present in the claim, the examiner notes that the disclosure of Abela merely indicates that the sleeve **may** be mirrored, thus this is not a requirement and may be omitted. Applicant's arguments regarding

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claim 13, rely on the deficiency of the rejection of claim 10. However, as claim 10 is properly rejected, the rejection of claim 13 is likewise proper.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spears et al in combination with Narciso, Jr. Spears et al teaches a device as claimed except the use of a perfusion channel and the particular lumen diameter. Narciso, Jr. teaches a device as claimed except the specific recitation that the fibers are removable and the lumen diameter. It would have been obvious to the artisan of ordinary skill to employ perfusion in the device of Spears et al, since this prevents tissue damage down stream of the treatment or alternatively to employ the manifestly insertable fiber of Spears et al in the device of Narciso, Jr., since Narciso, Jr. discusses no attachment of the fibers, and the catheter absent the fibers would be more flexible and thus more easily positioned, and in either case both to employ a lumen diameter in the claimed range, since this is an appropriate size to accommodate the guide wire and solves no particular problem in the art, thus producing a device such as claimed.

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spears et al in combination with Narciso, Jr, and Unger et al. The teachings of Narciso, Jr. and Spears et al and the motivation for combination and modification thereof are essentially those already set forth regarding claims 6-9. Unger et al teach the injection of a contrast agent followed by the infusion of an optically clear liquid. It would have been obvious to the artisan of ordinary skill to employ perfusion in the device of Spears et al, since this prevents tissue damage down stream of the treatment or alternatively to employ the manifestly insertable fiber of Spears et al in the device of Narciso, Jr., since Narciso, Jr. discusses no attachment of the fibers, and the catheter absent the fibers would be more flexible and thus more easily positioned, and in either

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case both to employ a lumen diameter in the claimed range, since this is an appropriate size to accommodate the guide wire and solves no particular problem in the art and to infuse the contrast agent followed by an optically clear fluid, since this enables better imaging, as taught by Unger et al and to repeat the procedure, since this provides no unexpected result and would enable the progress of the treatment to be observed, thus producing a method such as claimed.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spears et al in combination with Narciso, Jr., and Unger et al as applied to claims 1 and 3-5 above, and further in view of Chen et al. Chen et al teach the use of e.g. hematoporphyrin derivative as a photodynamic therapy compound. It would have been obvious to the artisan of ordinary skill to employ hematoporphyrin derivative in the combined method of Narciso, Jr. and Spears et al, since the method of Narciso, Jr. is dependant on no particular compound and since this compound is widely known for its efficacy in PDT, thus producing a method such as claimed.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abela in combination with Altman et al. Abela teaches a device such as claimed except for the syringes in the handle. Altman et al teach the employment of syringes in the handle of an infusion catheter. It would have been obvious to the artisan of ordinary skill to employ syringes in the handle of the catheter of Abela, since this would act as a unit and would not clutter the operating theater with additional lines or to employ the diffuser of Abela in the device of Altman et al, since this would enable, e.g. photodynamic treatment of the heart as is notorious in the art, official notice of which is hereby taken, thus producing a device such as claimed.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abela in combination with Altman as applied to claims 10-12 and further in combination with Tennican et

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al. Tennican et al teaches providing an indicator to show which syringe is outputting to the catheter. It would have been obvious to the artisan of ordinary skill to employ an indicator to show which syringe is currently active, since this will avoid confusion on the part of the physician, thus producing a device such as claimed.

Claims 14 and 15 are allowable over the art of record.

Applicant's arguments filed July 27, 2005 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

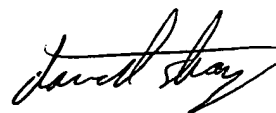
Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader, can be reached on Monday, Tuesday, Thursday, and Friday

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at (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
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